# UNITED STATES PATENT AND TRADEMARK OFFICE

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/806,186 | 03/23/2004 | Milan Graovac | 13180-30 | 2024 |

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| EXAMINER |
|---|
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| ART UNIT | PAPER NUMBER |
|---|---|
| 3736 | |

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|---|---|---|
| 3 MONTHS | 04/03/2007 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| | **Application No.** | **Applicant(s)** |
|---|---|---|
| *Office Action Summary* | 10/806,186 | GRAOVAC ET AL. |
| | **Examiner** | **Art Unit** |
| | Jeffrey G. Hoekstra | 3736 |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on <u>11 January 2007</u>.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,3 and 5-21* is/are pending in the application.

    4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3 and 5-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a)☐ All  b)☐ Some *  c)☐ None of:

      1.☐ Certified copies of the priority documents have been received.

      2.☐ Certified copies of the priority documents have been received in Application No. _____.

      3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

    * See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1)☐ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☒ Information Disclosure Statement(s) (PTO/SB/08)
    Paper No(s)/Mail Date _____.

4)☐ Interview Summary (PTO-413)
    Paper No(s)/Mail Date. _____ .

5)☐ Notice of Informal Patent Application

6)☐ Other: _____.

## DETAILED ACTION

### *Notice of Amendment*

1.     In response to the amendment filed on 01/11/2007, amended claim(s) 1, 7-10,

12, 13-17, and 19, and canceled claim(s) 2, 4, and 22-42 is/are acknowledged.  The

current rejections of the claim(s) 1, 3, and 5-21 is/are *withdrawn*.  The following new and

reiterated grounds of rejection are set forth:

### *Information Disclosure Statement*

2.     The information disclosure statement(s) (IDS) submitted on 01/11/2007 is/are

acknowledged.  The submission is in compliance with the provisions of 37 CFR 1.97

and 1.98.  Accordingly, the examiner is considering the information disclosure

statement(s).

### *Specification*

3.     The lengthy specification has not been checked to the extent necessary to

determine the presence of all possible minor errors.  Applicant's cooperation is

requested in correcting any errors of which applicant may become aware in the

specification.

### *Claim Objections*

4.     Claim 1 is objected to because of the following informalities:  the positive

recitation of "each finite element" in lines 5 and 10 and the positive recitation of "the

finite element" in line 8 both appear to lack antecedent basis and may render the claim indefinite. The Examiner notes Applicant may have intended the positive recitation of "each one of the plurality of finite elements". Appropriate correction is required.

5.      Claim 1 is objected to because of the following informalities: the positive recitation of "one weight factor" in line 5 and the positive recitation of "each weight factor" in line 8 both appear to lack antecedent basis and may render the claim indefinite. Appropriate correction is required.

6.      Claim 1 is objected to because of the following informalities: the positive recitation of "each current injection" in line 6 and the positive recitation of "the current injections" in lines 8-9 appears to lack antecedent basis and may render the claim indefinite. Appropriate correction is required.

7.      Claim 1 is objected to because of the following informalities: the positive recitation of "the current density" in line 7 appears to lack antecedent basis and may render the claim indefinite. Appropriate correction is required.

8.      Claims 1 and 15 are objected to because of the following informalities: the positive recitations of "the particular finite element density" and "the particular finite element" appear to lack antecedent basis and may render the claim indefinite. Appropriate correction is required.

9.      Claim 7 is objected to because of the following informalities: the positive recitation of "a physical model" in line 2 appears to duplicate the "model" positively recited in line 4 of claim 1 and may render the claim indefinite for failing to further limit independent claim 1. Appropriate correction is required.

10.     Claim 9 is objected to because of the following informalities:  the positive recitation of "the baseline electrical property is obtained using a finite element method" appears to duplicate the relationship positively set forth in claim 1 (e.g. the baseline electrical property is associated with a current injection which is associated with a corresponding weight factor and finite element) and may render the claim indefinite for failing to further limit independent claim 1.  Appropriate correction is required.

11.     Claims 13 and 14 are objected to because of the following informalities:  the positive recitations of "current injection electrode pairs" and "voltage measurement electrode pairs" appear to lack antecedent basis and may render the claims indefinite.  Appropriate correction is required.

12.     Claim 15 is objected to because of the following informalities:  the positive recitation of "a set of weights, , include" appears to be a typographical error. Appropriate correction is required.

13.     Claims 15 and 17 are objected to because of the following informalities:  the positive recitation of "the $k^{th}$ finite element" appears to lack antecedent basis and may render the claims indefinite.  Appropriate correction is required.

14.     Claim 15 is objected to because of the following informalities:  the positive recitation of "$i^{th}$ finite element" in at least lines 4-5 appears to lack antecedent basis and may render the claim indefinite.  Appropriate correction is required.

15.     Claim 15 is objected to because of the following informalities:  the positive recitation of "the current density" in line 6 appears to lack antecedent basis and may render the claim indefinite.  Appropriate correction is required.

16.     Claims 15 and 16 are objected to because of the following informalities:  the positive recitation of "the $i^{th}$ electrode pair" appears to lack antecedent basis and may render the claims indefinite.  Appropriate correction is required.

17.     Claim 16 is objected to because of the following informalities:  the positive recitation of "the impedance" in line 4 appears to lack antecedent basis and may render the claim indefinite.  Appropriate correction is required.

18.     Claims 20 and 21 are objected to because of the following informalities:  the positive recitation of "the possibility" appears to lack antecedent basis and may render the claims indefinite.  Appropriate correction is required.

### Claim Rejections - 35 USC § 103

19.     The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

20.     Claims 1-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shmulewitz et al (US 6,095,987) in view of Clay et al (IDS Non-Patent Literature, Cite 1: IEEE Transactions on Medical Imaging, Vol. 21, No. 6, June 2002).

21.     Shmulewitz et al discloses disease diagnosing bioimpedance analysis methods including the following:

22.     For claims 1, 3, and 7-9, Shmulewitz et al discloses disease diagnosing bioimpedance analysis methods, comprising:

- representing a body part, as *i* numbers of "compartments" as in Equation (2) in
  column 6, with a grid having a plurality of finite elements (column 6 line 30 – column
  7 line 9);

- obtaining a set of weights, $W_i$ as in Equation (2) in column 6, associated with a
  particular one of the plurality of finite elements using a model of the body part
  (column 6 line 30 – column 7 line 9);

- computing a diagnostic, I(t) as in Equation (2) in column 6, at the particular finite
  element, the diagnostic being a function of the set of weights, and a measured
  electrical property obtained with an electrode array (column 5 lines 43-65);

- utilizing the diagnostic (column 16 line 23 – column 17 line 26) to diagnose the
  possibility of disease in the body part; and

- obtaining a baseline electrical property, a conditioned impedance value (column 7
  lines 46-63), associated with the body part using a model, a control subject, or a
  finite element method (column 6 lines 50-64) thereof, wherein the diagnostic, I(t) as
  in Equation (2) in column 6, is a function of the baseline electrical property, the set of
  weights, and the measured electrical property obtained with the electrode array.

23.     For claims 10-11, Shmulewitz et al discloses disease diagnosing bioimpedance
analysis methods, wherein the baseline electrical property (column 7 lines 46-63) is
obtained assuming non-uniform resistivity (column 4 lines 24-36) by obtaining a
baseline voltage and using the baseline voltage to compute a baseline impedance
(column 8 lines 57-67).

24.    For claims 12-14, Shmulewitz et al discloses disease diagnosing bioimpedance

analysis methods, further comprising:

- applying a plurality of electrodes to the body part (column 5 lines 44-66);

- obtaining a measured electrical property of the body part with the plurality of

  electrodes (column 5 lines 44-66);

- wherein the step of applying includes applying current through each set of current

  injection electrode pairs on the body part and applying voltage measurement

  through each set of electrode pairs on the body part, wherein each of the current

  injection electrode pairs is associated with one of voltage measurement electrode

  pairs (column 5 lines 44-66 and column 8 line 57 – column 9 line 16); and

- wherein said step (g) further comprises starting the current injection process with

  one first pair of injecting electrodes and applying voltage measurement through one

  first pair of voltage measuring electrodes and repeating this process through $i$

  numbers of electrode pairs to obtain a measured impedance (column 5 lines 44-66

  and column 8 line 57 – column 9 line 16).

25.    For claims 15-21, Shmulewitz et al discloses the claimed disease diagnosing

bioimpedance analysis methods as aforementioned, *including*: (a) weighting measured

and calculated electrical parameters associated with electrode pairs and (b) using the

body part model to obtain a set of baseline impedances associated with electrode pairs,

*except* for explicitly disclosing: (a) using the body part model to obtain a set of current

densities, (b) calculating an average of the diagnostic function both as a global average

and as an average of the diagnostic computed at each finite element, (c) calculating a

second averaged diagnostic correlated to a homologous body part, (d) expressing the

diagnostic function in terms of an individual finite element as a calculated individual

impedance divided by the measured individual impedance, (e) calculating the difference

or difference divided by the averaged diagnostics between first and second averaged

diagnostics to indicate the possibility of disease in the body part or homologous body

part, and (f) the grid is a two- or three- dimensional.

26.     Clay et teaches disease diagnosing bioimpedance analysis methods including (a)

using the body part model to obtain a set of current densities (page 630 parts II.A. and

II.C.), (b) calculating an average of the diagnostic function both as a global average and

as an average of the diagnostic computed at each finite element (page 631 equation 8),

(c) calculating a second averaged diagnostic correlated to a homologous body part

(page 634 part D and Figure 3), (d) expressing the diagnostic function in terms of an

individual finite element as a calculated individual impedance divided by the measured

individual impedance via weighting (page 632 equation 18), (e) calculating the

difference or difference divided by the averaged diagnostics between first and second

averaged diagnostics (Tables I-IV) to indicate the possibility of disease in the body part

or homologous body part, and (f) a grid having a plurality of finite elements in either two

or three dimensions (page 630 Part II.B. and page 636 Part IV.).

27.     It would have been obvious to one having ordinary skill in the art at the time the

invention was made to modify the impedance based diagnostic method as taught by

Shmulewitz et al, with the impedance based diagnostic method as taught by Clay et al

for the purpose of increasing the efficacy of diagnosing disease based upon electrical

measurements taken on a body, using well-known finite element modeling mathematics, and using well-known finite difference modeling mathematics.

### *Response to Arguments*

28.     Applicant's arguments with respect to claims 1, 3, and 5-21 have been considered but are moot in view of the new ground(s) of rejection.

### *Conclusion*

29.     Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, .**THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not ·mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey G. Hoekstra whose telephone number is

(571)272-7232. The examiner can normally be reached on Monday through Friday, 8:00 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F. Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JH